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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/962,560	10/31/1997	DOUGLAS J HILTON	10976	9012

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EXAMINER	
CARLSON, KAREN C	

ART UNIT	PAPER NUMBER
1653	32

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/962,560	HILTON ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-55 and 58-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-55 and 58-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

This Office Action is in response to Paper #31, filed October 28, 2002. Claims 1-51, 56, and 57 have been canceled. Claims 52-55 and 58-70 are currently pending and are under examination.

Maintenance of Objections and Rejections

The disclosure is again objected to because of the following informalities: It is improper to incorporate sequences into the specification -see page 76, for example.

Appropriate correction is required.

Applicants urge that the Examiner has not explained why incorporation of sequences via accession numbers in improper at page 5, para. 5 of Paper #31. Applicants assert that those skilled in the art can obtain the sequences because they are accessible by the public. As noted by Applicants in their response (page 11) to the rejection of the claims under 35 USC 102(a), Schluter et al., the sequence defined by the accession number changes. Therefore, the sequences incorporated into the specification as intended by Applicants may not be the reference sequence now or in the future. Thus, this argument is not persuasive.

This application has been filed with informal drawings which are acceptable for examination purposes only. See the PTO-948 attached to Paper #15, mailed February 24, 2000. Formal drawings will be required when the application is allowed.

Applicants have not responded to this notice.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 62-67 are again rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-12 of prior U.S. Patent No. 6,323,317. This is a double patenting rejection.

Claim 62 is drawn to a protein comprising a SOCS box comprising amino acid sequence 52 or 55, or having 70% similarity to SEQ ID NO: 52 or 55. SEQ ID NO: 52 and NO: 55 are the same as patent sequences SEQ ID NO: 64 and NO: 67, respectively. Therefore, the limitations of Claim 62 is the same as patent Claims 3 and 4. SEQ ID NO: 52 is derived from mouse and rat, while SEQ ID NO: 55 is derived from human, and such corresponds to SEQ ID NO: 64 and NO: 67; therefore, Claim 64 is encompassed or inherent to patent Claims 3 and 4. The sequences of SEQ ID NO: 52 and 55 are found in the variables set forth for SEQ ID NO: 59 of patent Claims 1 and 2; therefore, when these variables are set to the amino acids depicted in SEQ ID NO: 52 and NO: 55 the claim limitations are the same.

Claim 65 is the same as patent Claim 5.

The limitations of Claim 66 are found in each of patent Claims 6 and 7.

The limitations of Claim 67, that the signal transduction is mediated by IL-6, are found in each of patent Claims 8, 9, and 10.

Instant Claim 63 is drawn to a protein comprising amino acid sequences SEQ ID NO: 4, NO:10, or NO:12, or sequences having 50% similarity thereto. These sequences are identical to patent SEQ ID NO: 4, NO: 10, and NO: 12 and therefore meet the limitations of patent Claim 11. These sequences are encoded by SEQ ID NO: 3, NO: 9, and NO: 11, respectively, which are the same as in the patent, and therefore limitations of patent Claim 12 are the same as Claim 63.

Applicants urge that whether two sets of claims are directed to identical to subject matter is to assess whether there is an embodiment that falls within one set of claims but not the other set. Applicants further state that members having 50% identity to SOCSI may be from a

different member of the SOCS family, that is, not a SOCS1 protein. Indeed, using variant language of "50% identity" may encompass many proteins that are not SOCS1, but the claims do not differentiate this. Therefore, this argument is not persuasive because, for example, SEQ ID NO: 4 is claimed as SEQ ID NO: 4 in patent claim 11, as are proteins having 50% identity to SEQ ID NO: 4. There is no distinguishing feature between the two sets of claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 63-67 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13-15 of U.S. Patent No. 6,323,317. Although the conflicting claims are not identical, they are not patentably distinct from each other because the SOCS1 protein set forth in SEQ ID NO: 4, NO: 10, and NO:12 comprise the SOCS box of patent Claims 1 and 2 (SEQ ID NO:59), of patent Claims 3 and 4 because these sequences comprise SEQ ID NO: 52 or NO: 55 which are the same as patent sequences SEQ ID NO: 64 and 67. Claims 65-67 depend from Claim 63 and have the same limitations as Claims 5-10. Patent Claims 13-15 are inherent to the sequences, and the specifications teaches that these sequences have the limitations of Claims 13-15. (see also the current nucleic acid claims describing these variables attributed to the protein sequences).

Applicants note (page 8) that a terminal disclaimer can be filed to overcome this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52-55 and 58-70 are again rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims do not present any structure and function relationship and therefore lack written description. For example, even though Claim 52 sets forth specific sequences for the SOCS box, the function of the full-length protein or variants thereof are not set forth, that is, suppressing cytokine mediated signaling is not meaningful because there are humdreds of known cytokines. The specification does not describe proteins having a percent similarity to a sequence having any function, or nucleic acids that hybridize under any conditions to a sequence and encoding a functional protein.

To overcome this rejection for lack of written description, Applicants should place a specific function in their claims. For example, "An isolated nucleic acid encoding a protein comprising a SOCS box comprising the amino acid sequence set forth in SEQ ID NO: 52 or SEQ ID NO: 55, wherein said protein inhibits IL-6-mediated signal transduction." The Examiner exemplified this claim language in the restriction requirement and in the previous Office Action, to aid Applicants in avoiding this rejection. Further, this problem of non-specific cytokine mediated signally was alluded to in the previous Office Action at page 2: Applicants do not expound on this capacity, that is, interleukin-6 versus TNF, growth hormone, glutamate, ion channel and so forth.

Applicants urge that suppression of cytokine mediated signaling is a function, and thus this rejection is overcome. To be more clear, if one skilled in the art were to set up an assay to determine if their protein having 90% identity to Applicants SEQ ID NO: 4 does or does not fall within the limitations of the claims, what assay should they perform? Should that artisan look for TNF mediated signal suppression by their protein? or growth hormone mediated signal suppression? There are hundreds of known cytokines – PDGF, VEGF, GM-CSF, and so on. What if their (the artisan's) protein inhibits one but not the other? How will we know that the SOCS box protein is yours or not? If the cytokine does not matter, declare so and let's move on.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65 and 66 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 65and 66, it is not clear what is meant by "modulates signal transduction". Is signal transduction augmented or attenuated? Does the activity occur insider or outside the cell? That is, receptor antagonism would also "modulate signal transduction".

Applicants state that Claims 65 and 66 have been canceled. Upon review of the file, it appears that these claims are still active. Thus, the rejection is maintained.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 52-55, 58, and 68-70 are again rejected under 35 U.S.C. 102(a) as being anticipated by Schluter et al. (January, 1996; Molecular Reproductive Development 43(1) 1-6). Schluter et al. teach nucleic acid submitted to GenBank as Z47352 (see page 2, col. 1 and the alignment attached to the reference. This nucleic acid sequence has 98.6% identity to SEQ ID NO: 3(**Claims 70, 52, 53, 54, 68, 69**). SEQ ID NO: 3 encodes SEQ ID NO: 4 which comprises a SOCS box comprising SEQ ID NO:52. The limitations of **Claims 55 and 58** describe the protein encoded by the nucleic acid, which has no bearing on the patentability of the nucleic acid sequence.

Claims 52-55, 58, and 68-70 are again rejected under 35 U.S.C. 102(a) as being anticipated by Schluter et al. (January, 1996; Molecular Reproductive Development 43(1) 1-6). Schluter et al. teach nucleic acid submitted to GenBank as Z46940 (see page 2, col. 1 and the alignment attached to the reference. This nucleic acid sequence has 99.3% identity to SEQ ID NO: 9 (**Claims 70, 54**). SEQ ID NO: 9 encodes SEQ ID NO:10 which comprises a SOCS box comprising SEQ ID NO:55 (**52, 53, 68, 69**). The limitations of **Claims 55 and 58** describe the protein encoded by the nucleic acid, which has no bearing on the patentability of the nucleic acid sequence.

Claims 52-55, 58, and 68-70 are again rejected under 35 U.S.C. 102(a) as being anticipated by Schluter et al. (January, 1996; Molecular Reproductive Development 43(1) 1-6). Schluter et al. teach nucleic acid submitted to GenBank as Z46939 (see page 2, col. 1 and the alignment attached to the reference. This nucleic acid sequence has 100% identity to SEQ ID NO:11 (**Claims 70, 54**). SEQ ID NO: 11 encodes SEQ ID NO: 12 which comprises a SOCS box comprising SEQ ID NO:52 (**Claim 52, 53, 68, 69**). The limitations of **Claims 55 and 58** describe the

protein encoded by the nucleic acid, which has no bearing on the patentability of the nucleic acid sequence.

Applicants address all 3 rejections under 35 USC 102(a) together at pages 11-12. Applicants observe that the sequences taught by Schluter et al. were changed after the January 1996 publication date, and that there is no indication that these accession numbers were made available to the public in January, 1996. Therefore, Applicants urge that these sequences were not available before their priority date and Schluter et al. is not prior art against their invention. The Examiner disagrees because the reference was clearly published in January, 1996; therefore, if the sequences were not available to the public, it would appear that reference would be senseless to those skilled in the art. This argument is not persuasive.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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January 24, 2003

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER